UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

BONNIE ROMERO, Plaintiff, vs. DENISE HANISCH, M.D.; and REGIONAL HEALTH PHYSICIANS, INC., d/b/a Edgemont Regional Medical Clinic and Custer Regional Medical Clinic, Defendants.	)	CIV. 08-5040-JLV ORDER DENYING MOTION TO STRIKE

INTRODUCTION

This matter is before the court pursuant to a motion to strike filed by defendant Dr. Denise Hanisch on August 18, 2010. (Docket 83). On August 20, 2010, the court held a hearing on the motion and requested supplemental briefing. (Docket 86). This matter has been fully briefed and is ripe for adjudication.

FACTS AND PROCEDURAL HISTORY

The court limits its recitation to those facts necessary to resolve Dr. Hanisch's pending motion. The court takes judicial notice of the facts in the record that are undisputed by the parties. These facts are contained in the parties' statements of material facts (Dockets 45, 52, & 60) and are set forth in the court's order dated May 3, 2010 (Docket 78).[1]

[1]The parties filed their statements of material facts in connection with Dr. Hanisch's motion for summary judgment (Docket 43). On May 3, 2010, the court denied Dr. Hanisch's motion. (Docket 78).

In 1999, Ms. Romero and her husband moved near Edgemont, South Dakota. Ms. Romero began treatment with Dr. Hanisch and the Edgemont Regional Medical Clinic. Dr. Hanisch is a licensed physician practicing medicine in South Dakota. At the times alleged in the complaint and up to August of 2006, Dr. Hanisch practiced medicine in Custer and Edgemont, South Dakota.

In September of 2000, Dr. Hanisch prescribed medication to Ms. Romero for the treatment of high cholesterol, a condition known as hyperlipidemia. From September of 2000 until December of 2006, while under the care of Dr. Hanisch, Ms. Romero continued to take a series of medications to treat her hyperlipidemia.

In October of 2004, Dr. Hanisch prescribed a combination of Zetia and Crestor, each to be taken once a day in 10 mg. doses. Two months later, Dr. Hanisch ordered a lipid profile test. Test results dated December 16, 2004, from the Custer Regional Hospital Laboratory indicated that Ms. Romero's ALT (alanine transaminase) and HDL (high density lipoprotein) levels were slightly elevated. On July 26, 2005, the Custer Regional Hospital Laboratory tested Ms. Romero's liver function, but not her lipid profiles. Dr. Hanisch noted on Ms. Romero's chart that "all labs are excellent" and that her liver function and lipids should be retested in a year.

On April 11, 2006, Ms. Romero went to the Edgemont Regional Medical Clinic for an annual physical examination, which included a review of her medications. A blood sample was taken, and Dr. Hanisch informed

Ms. Romero that all of her test results were normal.[2] Dr. Hanisch refilled all of Ms. Romero's medications for another year. Dr. Hanisch last treated Ms. Romero on April 11, 2006.

In December of 2006, Ms. Romero became ill while in Wisconsin and was diagnosed with acute hepatitis. Ms. Romero was referred to the Mayo Clinic. Due to failing liver function, Ms. Romero underwent an emergency liver transplant on January 28, 2007.

On April 2, 2008, Ms. Romero filed a complaint in this court against Dr. Hanisch and Regional Health Physicians, Inc., doing business as Custer Regional Medical Clinic and Edgemont Regional Medical Clinic.[3] (Docket 1). Ms. Romero asserted a claim of negligence against defendants, seeking to recover for alleged economic and non-economic losses, the loss of the ability to enjoy life, and the costs of the lawsuit including prejudgment interest. Id.

In support of her negligence claim, Ms. Romero alleged the following: (1) the incident which gave rise to the lawsuit occurred at Edgemont Regional Medical Clinic when Ms. Romero was under the professional care of

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[2]Ms. Romero denies that tests were performed as reported by Dr. Hanisch. The dispute as to whether Dr. Hanisch properly monitored the effects of Zetia and Crestor by routine liver function testing is at the heart of this lawsuit.

[3]The complaint named Regional Health Network, Inc., doing business as Custer Regional Hospital, as a defendant. On August 17, 2009, Regional Health Network, Inc., filed a motion for summary judgment (Docket 46), which Ms. Romero did not oppose (Docket 68). On February 5, 2010, the court granted the motion and dismissed Regional Health Network, Inc., as a party to this case. (Docket 70).

Dr. Hanisch; (2) the defendants owed a duty to Ms. Romero to exercise reasonable care and skill in providing professional medical services while she was a patient; (3) the defendants held themselves out as having the requisite medical skills and resources to care for and treat Ms. Romero, particularly to control and treat her cholesterol condition; (4) Dr. Hanisch breached the standard of care for a physician when she failed to properly diagnose, treat, care for, monitor, or transfer Ms. Romero; (4) Regional Health Physicians, Inc., breached the applicable standard of care for a medical care system by failing to administer the policies, procedures, and protocol necessary to properly diagnose, treat, and care for Ms. Romero; and (5) under the doctrines of *respondeat superior* and/or apparent agency, Regional Health Physicians, Inc., is liable for the acts and omissions of Dr. Hanisch and other personnel during their care and treatment of Ms. Romero. Id. Dr. Hanisch and Regional Health Physicians, Inc., filed separate answers denying liability and asserting various affirmative and other defenses. (Dockets 11 & 12).

On February 20, 2009, Ms. Romero disclosed her one and only expert witness in this case, Dr. Richard Kingston. (Docket 44-4). Dr. Kingston, a licensed pharmacist and clinical toxicologist, would testify as to the following: (1) the standard of care applicable to physicians like Dr. Hanisch in monitoring the safe and effective use of statin drugs such as Zetia and Crestor through routine liver function testing; (2) whether Dr. Hanisch breached this standard of care by failing to monitor properly Ms. Romero's liver function; and (3) whether this alleged breach caused Ms. Romero's liver failure. Id.; see also

Docket 89. He would also testify as to certain facts pertaining to Ms. Romero's medical history and records. (Docket 89 at pp. 4-6).

Dr. Hanisch moved for summary judgment on the grounds that Ms. Romero allegedly failed to present any *competent* expert witness testimony on the standard of care applicable to physicians and whether Dr. Hanisch breached the standard of care. (Dockets 43 & 44). Dr. Hanisch argued that Dr. Kingston, as a pharmacist, was incompetent *as a matter of law* to testify on these issues because he lacked the necessary training, education, and experience of a physician. (Docket 44 at p. 6). Ms. Romero resisted summary judgment. (Docket 51).

On May 3, 2010, the court entered an order denying Dr. Hanisch's motion for summary judgment. (Docket 78). The court found the Eighth Circuit did not have an absolute rule prohibiting pharmacists from testifying as expert witnesses in cases involving the alleged malpractice of physicians. Id. at p. 13. The court rejected Dr. Hanisch's argument that Dr. Kingston, as a matter of law, was precluded from testifying as an expert witness in this case simply because he was not a physician. Id. at p. 14. The court determined the key question was not whether a *pharmacist* could testify as to the issues in this case, but whether *Dr. Kingston* had the requisite knowledge, skill, experience, training, or education to qualify as an expert. Id. The court concluded such a question was best resolved by a Daubert[4] hearing, not by summary judgment. Id. The court scheduled a Daubert hearing for August 20, 2010.

[4]Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

On August 18, 2010, Dr. Hanisch filed a motion to strike Dr. Kingston as an expert witness in this case. (Docket 83). Dr. Hanisch raised essentially the same arguments advanced in support of her summary judgment motion. Compare Docket 84 with Docket 44. Ms. Romero resisted the motion to strike (Docket 85) on the basis of the court's previous order denying summary judgment (Docket 78). On August 20, 2010, the court conducted a Daubert hearing to determine if Dr. Kingston qualified as an expert witness in this case. At the conclusion of the hearing, the court ordered supplemental briefing.

Dr. Kingston's Qualifications

Dr. Kingston graduated from the University of New Mexico with an undergraduate degree in pharmacy. (TT 5:17-19).[5] During his final year of study, Dr. Kingston chose clinical pharmacy as his practice area. (TT 5:23-25; 6:1-4). Clinical pharmacy is the clinical application of monitoring the safe and effective use of pharmaceuticals and advising as to regular and routine use of pharmaceuticals. (TT 6:6-8). Clinical pharmacy typically is used in a patient-oriented care setting in collaboration with other medical practitioners. (TT 6:8-11). Dr. Kingston's training in clinical pharmacy occurred in a clinical setting. (TT 6:12-14). He collaborated with doctors, nurses, and other medical practitioners for the benefit of the patient. (TT 6:18-24).

[5]The court shall cite to the transcript of the Daubert hearing as "TT" followed by the page number(s) where the corresponding information may be found. For example, information found on lines 17-19 of page 5 of the transcript shall be cited to as "TT 5:17-19."

Dr. Kingston received a doctorate in clinical pharmacy from the University of Minnesota. (TT 7:1-6, 15-16). The university operated the clinical pharmacy program in conjunction with the school of medicine in that students of both programs initially took the same classes and exams. (TT 7:5-10). When the time came for medical students to go on their rotations, clinical pharmacy students then would study their area of specialization–the application and therapy of drugs. (TT 7:10-14).

Upon obtaining his doctorate degree, Dr. Kingston completed a residency and a combined post-doctoral fellowship in clinical phamacokinetics and clinical toxicology. (TT 7:15-19; 8:24-25). Clinical pharmacokinetics is the study of the absorption, distribution, elimination, and metabolism of drugs. (TT 7:22-25). The field is "focused on understanding the mechanistic operation of what happens to the drug when it gets in the bloodstream or when it gets into the body, when it's introduced in the body; where it goes, how it's metabolized, where it concentrates, where the site of action is going to be, applying mathematical equations, and the like, to predict certain types of blood levels." (TT 7:25; 8:1-6). The goal of Dr. Kingston's study in this field was to tailor drug administration to meet a patient's individual needs. (TT 8:18-22).

During his fellowship, Dr. Kingston led the clinical toxicology treatment team at the St. Paul-Ramsey Medical Center, a trauma center affiliated with the University of Minnesota. (TT 8:15-18; 9:1-2). Dr. Kingston coordinated and worked with a team of experts for the treatment of poison patients. (TT 9:2-8). Dr. Kingston consulted with medical doctors on a daily basis, offering advice on

all aspects of drug therapy and administration. (TT 9:9-15). For example, Dr. Kingston advised medical doctors as to the which drugs to prescribe and in what dosages, how to administer the drug, and how to monitor the ongoing safety and efficacy of drugs. (TT 9:19-24; 10:711). Dr. Kingston made recommendations as to the use of drugs as a component of the ongoing therapy of patients. (TT 10:11-15).

While engaged in his post-doctoral studies, Dr. Kingston was also a member of the teaching program at the University of Minnesota and St. Paul-Ramsey Medical Center. (TT 10:20-23). Dr. Kingston later became a full-time faculty member of the University of Minnesota, training and educating medical practitioners such as physicians, nurses, respiratory therapists, and pharmacists, within the university and affiliated medical centers. (TT 11:1-24). During this time, Dr. Kingston continued his collaborative work at the St. Paul-Ramsey Medical Center. (TT 11:2-5). Dr. Kingston eventually rose to rank of full professor. (TT 12:22-25). He maintained a joint appointment as the first director of the Minnesota Poison Control System and its regional poison center, which serviced a five-state region, and as a clinical pharmacologist at inpatient care clinics at the medical center. (TT. 13:6-18). As a member of the clinical pharmacology unit, Dr. Kingston consulted with and advised medical professionals on which drugs to prescribe, the proper use of drugs, and how to monitor drugs for safety. (TT 13:20-24). The clinical pharmacology unit also conducted extensive research on, for example, the safe and effective use of antibiotics. (TT 14:1-10). Through its research, the unit changed the standard

for care for physicians and other medical professionals prescribing antibiotics. (TT 14:11-21). The unit changed the standard of care as to the monitoring of antibiotics and the appropriate dosages. (TT 14:13-15).

During the course of his career, Dr. Kingston has advised on the use and safety of statin drugs. (TT 15:17-20). Dr. Kingston and his colleagues also formed a company called SafetyCall International, a professional medical practice and poison center affiliated with the University of Minnesota. (TT 16:1-3; 17:9-10). Dr. Kingston is president of the company. (TT 16:17). The company is licensed with the boards of medicine, pharmacy, and veterinary medicine and "specializes in post market medical surveillance and monitoring the safety of a variety of different types of drugs, chemicals, [and] poisons . . . ." (TT 16:18-19; 17:10-12). In part, Dr. Kingston directs a primary practice group of clinicians, comprised of physicians, pharmacists, and veterinarians, who collaborate and consult with patients, treating physicians, medical providers, and drug companies on the safe and effective use of drugs. (TT 18:1-23). As a member of the senior staff, Dr. Kingston personally consults with and advises medical doctors and others as to the safe and effective use of drugs, including statin drugs. (TT 17:16-22). Dr. Kingston also maintains his position as a professor at the University of Minnesota, educating clinical practitioners, pharmacists, physicians, and others on the safe and effective use of drugs, including statin drugs. (TT 23:1-7). Dr. Kingston has published extensively on the safety and efficacy of drugs, often in consultation with medical doctors. (TT 23:18-25; 24:1-4).

Dr. Kingston has advised medical doctors as to the safety and efficacy of the drugs prescribed in this case, Crestor and Zetia, and how to monitor and test those drugs. (TT 25:20-25; 26:1-7). Dr. Kingston is familiar with the standard of care of physicians in administrating and monitoring Crestor and Zetia. (TT 26:9-15). Dr. Kingston has instructed and routinely advised physicians and other medical professionals on the importance of complete and accurate charting of information regarding the safe and effective administration of drugs, including drug uses, doses, decimal points, and drug monitoring parameters. (TT 42:5-25; 43:1-25). In numerous cases, Dr. Kingston has been qualified and allowed to testify as an expert witness on the standard of care applicable to practicing physicians with respect to the care and treatment of patients, including, but not limited to, the monitoring of drugs. (TT 47:12:25; 48:1-10). In such cases, Dr. Kingston was either the sole expert or one expert testifying as to the standard of care applicable to physicians. (TT 48:16-25). In cases where the diagnosis of a particular condition was at issue, a physician was qualified as an expert witness, with Dr. Kingston offering expert testimony as to the use of drugs as part of a treatment regimen. (TT 48:19-24).

The only professional license Dr. Kingston holds is in pharmacy–he is not licensed to make a medical diagnosis and does not hold medical staff privileges

at any hospital. (TT 51:3-21; 53:18-20). In his independent practice, he is not permitted to prescribe medications for patients. (TT 51:18-25; 52:1-7).[6]

Dr. Kingston's Opinions

As stated previously, Dr. Kingston is familiar with the standard of care for physicians in administrating and monitoring Crestor and Zetia. (TT 26:9-15). In Dr. Kingston's professional opinion, "[t]he standard of care is that first you ensure that the drug you are recommending meets the intended goal and that it produces the desired effect and that it continues to produce the desired effect. And secondly, that you monitor the patient for a potential adverse effects." (TT 26:17-21). In Dr. Kingston's professional opinion, a liver function test is the most routinely used method of monitoring the potential adverse effects of Crestor and Zetia. (TT 26:22-25). In Dr. Kingston's professional opinion, based on the standard of care applicable to physicians, a physician should test a patient's liver function when on Crestor and Zetia in accordance with the following schedule: "they [the patient] would be tested for baseline; they would be followed up in 12 weeks after that, and then rechecked at six months in therapy, and then periodically thereafter, which can be at least annually." (TT 40:19-25; 41:1-4). Dr. Kingston opined that Dr. Hanisch "did not follow the standard of care related to the safe and effective use of the anti-

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[6]In Dr. Kingston's deposition, he indicated he could prescribe certain medications to patients under the authority of and in collaboration with physicians. (Exhibit 6 to the Daubert hearing, p. 13 of the transcript, lines 18-25, and page 14 of the transcript, lines 1-12). Although Dr. Kingston independently cannot prescribe prescription drugs, it is unclear whether he can prescribe prescription drugs under the authority of a licensed physician. See TT 51:22-25; 52:1-7.

lipidemic drugs, anticholesterol drugs" because she allegedly did not properly monitor and test Ms. Romero's liver function. (TT 25:11-15; 27:1-9; 41:5-6). Dr. Kingston opined that the drugs Zetia and Crestor caused Ms. Romero's liver failure. (TT 36:7-11). Dr. Kingston also opined that Dr. Hanisch did not accurately and thoroughly chart Ms. Romero's medical information. (TT 44:1-4).

DISCUSSION

At the conclusion of the Daubert hearing, the court ordered supplemental briefing. In her brief, Ms. Romero indicated Dr. Kingston would testify as to three issues: (1) the standard of care applicable to physicians like Dr. Hanisch in monitoring the safe and effective use of statin drugs such as Zetia and Crestor through routine liver function testing; (2) whether Dr. Hanisch breached this standard of care by failing to monitor properly Ms. Romero's liver function; and (3) whether this alleged breach caused Ms. Romero's liver failure. (Docket 89). Dr. Hanisch raised three primary challenges to the designation of Dr. Kingston as an expert witness in this case. (Docket 92). Dr. Hanisch challenged whether Dr. Kingston is competent to testify as an expert witness, whether he is qualified to testify as an expert witness under Fed. R. Evid. 702, the rule governing the admissibility of expert testimony, and whether his testimony is reliable under Rule 702. Id. The court will address each challenge in turn.

A. Whether Dr. Kingston is Competent to Testify as an Expert Witness

Dr. Hanisch argues that Dr. Kingston is not competent to testify as to the standard of care applicable to physicians because he is not a physician.

However, Dr. Hanisch does not argue Dr. Kingston is incompetent to testify on the issues of breach and causation. See generally Docket 92.

In support of her argument, Dr. Hanisch relies primarily on Fed. R. Evid. 601, case law from other circuits interpreting Rule 601, her interpretation of the substantive law of South Dakota, and case law from other state courts. Id. at pp. 1-8. Rule 601 provides as follows:

> Every person is competent to be a witness except as otherwise provided in these rules. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the competency of a witness shall be determined in accordance with State law.

Fed. R. Evid. 601.

The court does not consider Rule 601 to be a bar to Dr. Kingston's testimony. Nor does the substantive law of South Dakota preclude Dr. Kingston from testifying as a competent witness in this case. As stated in the court's previous order, see Docket 78, in diversity actions such as this one, courts apply federal procedural rules, but state substantive law. Sosna v. Binnington, 321 F.3d 742, 744-45 (8th Cir. 2003) (citing Erie Railroad Co. v. Tompkins, 304 U.S. 64, 78 (1938) and Potts v. Benjamin, 882 F.2d 1320, 1324 (8th Cir. 1989)). Under South Dakota law, the elements of negligence are standard of care, breach, causation, and injury. Koeniguer v. Eckrich, 422 N.W.2d 600, 601-02 (S.D. 1988). "The negligence standard for doctors is no different than that for other professionals." Magbuhat v. Kovarik, 382 N.W.2d 43, 46 (S.D. 1986) (additional citations omitted). "The issue on which the jury should be instructed in a medical malpractice action is whether the doctor

deviated from the required standard of care."[7] Id.; see also Schrader v. Tjarks, 522 N.W.2d 205, 210 (S.D.1994) ("In a medical malpractice case, plaintiff has the burden to show whether the doctor deviated from the required standard of care.") (internal quotation marks omitted). Deviation from the standard of care "is not conditioned on bad faith or the physician's state of mind at the time of the alleged negligence." Magbuhat, 382 N.W.2d at 46.

Under South Dakota law, the use of expert witnesses in medical malpractice cases is well established:

> The general rule in medical malpractice cases is that negligence must be established by the testimony of medical experts. . . . [A] verdict in a malpractice case based on inferences stemming from speculation and conjecture cannot stand. However, expert evidence is not exclusively required to establish negligence. For example, if a physician operates on a patient's knee, testimony of lay witnesses could establish that the wrong knee was treated without indulging in speculation and conjecture or knowledge beyond a layperson's realm.

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[7]Under South Dakota law, the general standard of care for physicians is as follows:

> In performing professional services for a patient, a physician has the duty to possess that degree of knowledge and skill ordinarily possessed by physicians of good standing engaged in the same line of practice in the same or similar locality.
>
> A physician also has the duty to use that care and skill ordinarily exercised under similar circumstances by physicians in good standing engaged in the same line of practice in same or similar locality and to be diligent in an effort to accomplish the purpose for which the physician is employed.
>
> A failure to perform any such duty is negligence.

South Dakota Pattern Jury Instructions ("SDPJI") 20-70-30; see also Martinmaas v. Engelmann, 612 N.W.2d 600 (S.D. 2000).

> The rule does not exclude the opinions and conclusions of lay witnesses on subjects which are within the common knowledge and comprehension of persons possessed of ordinary education, experience and opportunity.

Id. (internal citations omitted); see also Koeniguer, 422 N.W.2d at 601-02 (noting expert testimony typically was required on the question of causation, the relevant standard of care, and any breach of the standard of care); Lohr v. Watson, 2 N.W.2d 6, 7 (S.D. 1942) (same).

In support of her position, Dr. Hanisch cites to SDPJI 20-70-20, which provides in part, "You must decide whether the defendant possessed and used the knowledge, skill, and care which the law demands based on the testimony and evidence of members of the profession who testified as expert witnesses." SDPJI 20-70-20. Dr. Hanisch interprets "members of the profession" to mean, for example, that only a physician may provide expert testimony on the standard of care applicable to other physicians. (Docket 92 at p. 3). The court believes Dr. Hanisch reads the phrases "medical experts" and "members of the profession" too narrowly. One cannot seriously argue that a licensed pharmacist and clinical toxicologist is not a medical expert. Dr. Hanisch cites no authority where any South Dakota court has stated that a non-physician is not a medical expert and cannot testify as a matter of law as to the standard of care applicable to physicians. Nor has the court in its independent research found any such authority. Further, the court is unaware of any case where the

South Dakota courts have defined the scope of "members of the profession."[8] Dr. Kingston is certainly a member of the medical profession, although not a member of the same school of practice as Dr. Hanisch.[9]

The court weighs heavily the underlying rationale for the expert witness requirement. The purpose of the requirement "is that layman are not qualified

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[8]Dr. Hanisch cites to Lenius v. King, 294 N.W.2d 912 (S.D. 1980), a legal malpractice case, in support of her argument that only physicians may offer expert testimony on the standard of care applicable to physicians. (Docket 92 at pp. 2-3). In Lenius, the trial court granted defendant's motion for a judgment notwithstanding the verdict because plaintiff failed to present any expert testimony that the defendant breached the standard of care applicable to attorneys. 294 N.W.3d at 913. The trial court approved of a jury instruction which stated in part, "You must decide whether the defendant possessed and used the knowledge, skill and care which the law demands of him from the evidence of attorneys who testified as expert witnesses." Id. On appeal, plaintiff challenged this jury instruction, arguing expert testimony was not required to establish the standard of care. Id. The state supreme court upheld the jury instruction, finding the malpractice claims were so complex as to require expert testimony to establish the standard of care applicable to attorneys. Id. at 914. The state supreme court noted the trial court applied the same standard of care required of a lawyer as required of the medical profession. Id.

The court does not find Lenius to be on point with this case. The issue in Lenius was not whether an expert was competent to testify, but whether expert testimony was required at all. The challenge was not to whether, for example, a paralegal could testify as to the standard of care applicable to attorneys. The state supreme court upheld the jury instruction because it determined expert testimony, rather than lay testimony, was required, *not* because it determined only attorneys could offer expert testimony in a malpractice case involving an attorney. Thus, the court will not extend the holding in Lenius to create law in this case.

[9]The court also notes that, in pursuing his undergraduate degree, Dr. Kingston initially took the same courses and examinations as medical students.

by learning and experience to judge the medical aspects of such cases." Block v. McVay, 126 N.W.2d 808, 810 (S.D. 1964), *overruled on other grounds by* Shamburger v. Behrens, 380 N.W.2d 659 (S.D.1986); see also Van Zee v. Sioux Valley Hospital, 315 N.W.2d 489, 492 (S.D. 1982) ("What this means is that ordinarily laymen are not qualified to say that a good doctor would not go wrong, and that expert testimony is indispensable before any negligence can be found."). Dr. Kingston is not a layman. Without a definitive statement from the South Dakota Supreme Court indicating otherwise, this court cannot see how the expert witness requirement precludes a licensed pharmacist like Dr. Kingston from qualifying as a competent expert witness in this case. The court will not resort to the outcome determinative step of excluding an expert witness on the basis of state law when no such law exists.

The court addresses one final matter. In support of her position, Dr. Hanisch cites to several cases from courts in other states. This authority is not binding as it is not the law of South Dakota. Most of the cases cited by Dr. Hanisch dealt with whether non-physicians were competent to testify as to the standard of care applicable to physicians in diagnosing ailments and prescribing medications. See, e.g., Bell v. Hart, 516 So.2d 562 (Ala. 1987); Rodriguez v. Jackson, 574 P.2d 481, 485 (Ariz. Ct. App. 1978). Dr. Kingston will not testify as to these issues and may or may not be competent to do so. However, Dr. Kingston is competent to testify as to a physician's standard of care in monitoring the safe and effective use of statin drugs. The court extensively outlined Dr. Kingston's qualifications, which will not be repeated

here, but it bears mentioning that Dr. Kingston has spent his career studying and advising medical professionals as to the safety and efficacy of drugs and, perhaps most important, is familiar with and knowledgeable about a physician's standard of care on this subject.

B. Whether Dr. Kingston is Qualified to Testify as an Expert Witness

As a preliminary matter, the court notes the proponent of the expert testimony, here, Ms. Romero, must prove its admissibility by a preponderance of the evidence. Lauzon v. Senco Products, Inc., 270 F.3d 681, 686 (8th Cir. 2001); see also Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 757-58 (8th Cir. 2006) (same). Dr. Hanisch challenges whether, under Rule 702, Dr. Kingston is qualified to testify as an expert witness on the issues of standard of care, breach, and causation. Dr. Hanisch argues Dr. Kingston is not *qualified* to be an expert witness because he is not *competent* to be an expert witness. (Docket 92 at p. 11). As the court found Dr. Kingston to be a competent expert witness in this case, Dr. Hanisch's argument is moot. In any event, in accordance with Rule 702, the court finds Dr. Kingston is qualified by virtue of his knowledge, skill, experience, training, and education to offer expert testimony on the following subjects: (1) the standard of care applicable to physicians like Dr. Hanisch in monitoring the safe and effective use of statin drugs such as Zetia and Crestor through routine liver function testing; (2) whether Dr. Hanisch breached this standard of care by failing to monitor properly Ms. Romero's liver function; and (3) whether this alleged breach caused Ms. Romero's liver failure.

The court incorporates by reference the detailed recitation of Dr. Kingston's qualifications set forth previously in this opinion. However, it bears repeating that Dr. Kingston has spent his career studying and monitoring the safe and effective use of drugs, advising medical professionals including physicians on the safe and effective use of drugs, collaborating with medical professionals on courses of treatment for patients, and studying the effects of drugs, including statin drugs, on the human body. Dr. Kingston possesses the necessary qualifications to offer expert testimony in this case.

C. Whether Dr. Kingston's Testimony is Reliable

Finally, Dr. Hanisch challenges whether Dr. Kingston's testimony as to standard of care and causation is reliable under Rule 702, Daubert, and its progeny.

Rule 702 states as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The court "must ensure that any and all scientific testimony or evidence admitted is not only relevant,[10] but reliable." Daubert, 509 U.S. at

[10]Rule 702 also requires expert testimony to be relevant, that is, to "assist the trier of fact to understand the evidence or to determine a fact in issue." Daubert, 509 U.S. at 591 (internal quotation marks omitted). "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Id. at 591-92. The issue is one of "fit." Id. at 591.

589.[11] The subject of an expert's testimony must be scientific, technical, or other specialized knowledge. Id. at 589-90. This requirement "establishes a standard of evidentiary reliability."[12] Id. at 590; see also Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (noting it is the word "knowledge" in Rule 702 that establishes a standard of evidentiary reliability). " '[S]cientific' implies a grounding in the methods and procedures of science." Daubert, 509 U.S. at 590. " '[K]nowledge' connotes more than subjective belief or unsupported speculation," although the subject of the testimony need not be known to a certainty. Id. In order to be "scientific knowledge," an assertion or inference must be derived by the scientific method. Id. "Proposed testimony must be supported by appropriate validation-*i.e.*, 'good grounds,' based on what is known." Id. Expert evidence is unreliable, and thus inadmissible, "if it

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Fed. R. Evid. 402 states, in pertinent part, "All relevant evidence is admissible . . . ." See Fed. R. Evid. 402. Fed. R. Evid. 401 defines "relevant evidence" as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." See Fed. R. Evid. 401. Dr. Hanisch does not challenge the relevancy of Dr. Kingston's testimony. (Docket 92 at pp. 10, 22).

[11]Although Daubert deals specifically with expert testimony based on scientific knowledge, the Supreme Court extended the principles in Daubert to all expert testimony in Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 141 (1999).

[12]An expert witness, unlike an ordinary witness, may offer opinions not based on firsthand knowledge or observation. Daubert, 509 U.S. at 592. It is presumed the expert's opinion "will have a reliable basis in the knowledge and expertise of his discipline." Id. Therefore, the fact that Dr. Kingston personally did not treat Ms. Romero and did not observe her symptoms firsthand is not an impediment to being an expert witness.

is speculative, unsupported by sufficient facts, or contrary to the facts of the case." United States v. Bailey, 571 F.3d 791, 803 (8th Cir. 2009); see also United States v. Two Elk, 536 F.3d 890, 904 (8th Cir. 2008) (" '[N]othing in Rule 702, *Daubert*, or its progeny requires that an expert resolve an ultimate issue of fact to a scientific absolute in order to be admissible.' ") (quoting Kudabeck v. Kroger Co., 338 F.3d 856, 861 (8th Cir. 2003)).

In sum, "[f]aced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a),[13] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Daubert, 509 U.S. at 592. "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93.

To make this determination, a district court may evaluate one or all of the following non-exclusive factors: (1) whether the theory or technique can be

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[13]Fed. R. Evid. 104(a) provides:

> Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining conditional admissions]. In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Fed. R. Evid. 104(a). "These matters should be established by a preponderance of proof." Daubert, 509 U.S. at 592, n. 10 (citing Bourjaily v. United States, 483 U.S. 171, 175-76 (1987)).

or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and whether there are standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community.[14] Id. at 593-94. A district court may consider all or none of these factors; a court should consider them in cases "where they are reasonable measures of the reliability of expert testimony." Kumho, 526 U.S. at 152. The applicability of these factors will depend on the particular facts of the case. Id. at 150-51.

The Court of Appeals for the Eighth Circuit gives "great latitude" to district courts in determining whether expert testimony satisfies the requirements of Rule 702. Allen v. Brown Clinic, P.L.L.P., 531 F.3d 568, 573 (8th Cir. 2008) (citing Craftsmen Limousine, Inc. v. Ford Motor Co., 363 F.3d 761, 776 (8th Cir. 2004)). Regardless of what factors are evaluated, the main inquiry is whether the proffered expert's testimony is sufficiently reliable. Id. at 574 (citing Unrein v. Timesavers, Inc., 394 F.3d 1008, 1011 (8th Cir. 2005)

[14]" 'General acceptance' is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence, but the Rules of Evidence–especially Rule 702–do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." United States v. Rodriguez, 581 F.3d 775, 794 (8th Cir. 2009) (quoting Daubert, 509 U.S. at 597). " 'Pertinent evidence based on scientifically valid principles will satisfy those demands.' " Id. (quoting Daubert, 509 U.S. at 597).

("There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant.")).

Rule 702 requires a flexible approach. Daubert, 509 U.S. at 594. The focus of Rule 702 "must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. at 596; see also Two Elk, 536 F.3d at 903 (A district court " 'must exclude expert testimony *if it is so fundamentally unreliable that it can offer no assistance to the jury*, otherwise, the factual basis of the testimony goes to the weight of the evidence.' ") (emphasis in original) (quoting Larson v. Kempker, 414 F.3d 936, 940-41 (8th Cir. 2005)).

Dr. Hanisch argues Dr. Kingston's testimony regarding the standard of care is unreliable because he merely "parrots" and relies exclusively on the drug manufacturer's recommendations regarding liver function testing expressed in the package insert. (Docket 92 at pp. 15-19). Dr. Hanisch misconstrues Dr. Kingston's testimony. Dr. Kingston repeatedly testified at the Daubert hearing that he relied on his training, knowledge, and experience in forming his opinions as well as relying on relevant literature, Ms. Romero's medical records, and the drug manufacturer's insert. Thus, the drug manufacturer's insert was but one factor in Dr. Kingston's analysis, and it was proper for him to consider it.

The court finds the reasoning underlying Dr. Kingston's testimony is valid and properly applied to the facts of the case. The standard of care regarding the monitoring of statin drugs appears to have been tested and subjected to peer review and publication. Further, Dr. Hanisch provided no expert testimony to contradict Dr. Kingston's opinion regarding the standard of care. Instead, Dr. Hanisch provided excerpts from articles published in scientific journals that appear to challenge the existing standard of care. These articles discuss whether it is necessary and cost-effective to routinely monitor the effects of statin drugs, not whether such monitoring is the standard of care. Thus, absent evidence to the contrary, it appears the standard of care espoused by Dr. Kingston has been accepted generally in the medical community, although new challenges arise as to its continued application.

Dr. Hanisch also argues Dr. Kingston's testimony regarding causation is unreliable because he is not a hepatologist, pathologist, or family doctor; he never examined Ms. Romero; and he disagrees with the conclusion of the hepatologist who examined Ms. Romero's liver that he could not determine if the statin drugs caused Ms. Romero's liver failure. Id. at p. 24. The court finds these challenges go to the weight of Dr. Kingston's testimony, not its admissibility. Dr. Kingston has spent his career studying the effects of drugs, including statin drugs, on patients. As a pharmacist and clinical toxicologist, he is qualified to testify as to causation in this case. Vigorous cross-examination is the appropriate method of challenging Dr. Kingston's testimony.

CONCLUSION

In accordance with the above discussion, it is hereby

ORDERED that Dr. Hanisch's motion to strike (Docket 83) is denied. Dr. Kingston shall be allowed to testify as to (1) the standard of care applicable to physicians like Dr. Hanisch in monitoring the safe and effective use of statin drugs such as Zetia and Crestor through routine liver function testing; (2) whether Dr. Hanisch breached this standard of care by failing to monitor properly Ms. Romero's liver function; and (3) whether this alleged breach caused Ms. Romero's liver failure.

Dated December 3, 2010.

BY THE COURT:

/s/ *Jeffrey L. Viken*
JEFFREY L. VIKEN
UNITED STATES DISTRICT JUDGE